

April 21, 1999

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William K. Hubbard  
Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Federal Register Request for Information: Performance Standard for *Vibrio Vlnificus*.  
Docket Number 98P-0504 – Volume 64, Number 13, Page 3300-3301.

Dear Mr. Hubbard,

I am writing to respond to the special interest group, Center for Science in the Public Interest's (CSPI's) proposal to treat all shellfish with pasteurization before distribution. I want to state up-front that I am opposed to this idea, and believe the shellfish growers on the West Coast have acted diligently to eliminate risks associated with shellfish related illnesses.

At the Washington State Sea Grant 9<sup>th</sup> Conference this year, Bob Price of Sea Grant Marine Extension spoke on "Food-Borne Illness and Shellfish". During his presentation he stated that "the commissioner of the FDA had stated that shellfish are now one of the safest forms of protein". He also showed statistics on other foods and food sources that have steadily increased in terms of food illness cases per year. If this is the case, why is the FDA considering implementing a pasteurization process in an area where there does not appear to be a need? Would it not be better to focus on those foods or food sources that are a problem based upon statistical probability of causing illness?

The suggested pasteurization method is a patented process that according to Haejung An of the Oregon State university Seafood Lab in Astoria Oregon would cost Approximately \$250,000 to license, not including the actual cost of the device. If this method is required, my company and many others will cease operation. The majority of shellfish farmers are smaller types, and this type of expenditure would cause them to incur a level of debt that they could never justify financially. It has been stated that if this pasteurization process is required, it would add \$.08 to each individual shellfish treated. It has also been suggested by CSPI that the end customer would be willing to pay this added cost. This is not the case, and I believe the following situation demonstrates this. One bushel of oysters contains 150 oysters on average, which would result in an additional \$12.00 per bushel of processed oysters. This year we saw our price reduced from \$18 per bushel to \$15.50, a 14% reduction in wholesale price. There is an obvious contradiction here between the suggestion by CSPI, and the real world customer in terms of passing this cost onto the end user. In reality, the added cost due to pasteurization would be absorbed by the shellfish producer, and this would put the majority of us at a profit margin that would require us to stop farming.

Another issue is the quality of the product. This process kills the shellfish treated. In the case of oysters, a rubber band eliminates the appearance of a dead product by holding the shell closed. Additionally, I understand that while the flavor of the oyster immediately after treatment is reasonably aligned with that of a live oyster, this taste soon gives way to a flavor more aligned

98P-0504

C 231

with a rubber type product. If you are an oyster connoisseur, I doubt very much that this would be an enjoyable experience for your taste buds, and would it be worth an additional \$.08 to experience an degraded taste?

Shellfish growers on the West Coast have been very diligent in responding positively and proactively to any problems. Our policy has always been that if there is a problem, stop and solve the problem. We act to go beyond governmental agency requirements to assure our product is safe, and of the highest quality. We work closely with all local, state, and federal agencies to develop the best management practices, and to assist in many studies, and monitoring activities. We are constantly plagued by bad news from the East Coast, where requirements on growers do not appear to adequately address eliminating tainted shellfish from distribution channels. The west coast has not had this problem, due mostly to the fact that the ecology is different here, and because the growers have acted responsibly in assuring only safe shellfish are distributed to customers. Unfortunately, whenever there is a problem with shellfish the media assures that the entire country is informed of the problem, with no specifics on the area where the tainted shellfish originated. This has caused markets for west coast shellfish to be severely affected, when in reality our shellfish are safe to consume.

I must also state that I suspect there are considerable financial gains to the developer of the pasteurization process, the AmeriPure Company. It is my understanding that for several years this company has been pressuring to have the pasteurization process required. I have a background in Mechanical Engineering, and am a licensed Professional Engineer in the state of Washington. In my previous career as an engineer, I worked extensively in the new product development area, and am very familiar with tactics used by companies to assure product success. One of the most common tactics is to have that product required in a particular industry. As a Chief Engineer, I witnessed many marketing types successfully attempt to achieve this goal by doing exactly what AmeriPure is doing. I find this to stretch the limits from a professional and business ethics standpoint, and believe CSPI may be being used as a front for this action. I have no doubt that CSPI serves as a valuable contributor to the safety of the public, however in this case there appears to be questionable agenda items involved.

In closing, I would like to repeat that I am opposed to requiring pasteurization of shellfish products on the West Coast. We have demonstrated a proactive and responsible approach to dealing with potential problems with our products. Requiring this process would act to eliminate many growers from farming, and degrade the taste and quality of the treated product, while addressing a safety issue on the West Coast that does not exist.

Best Regards,



Brian Sheldon  
Northern Oyster Company  
Sheldon Marine Enterprises  
PO Box 1039  
Ocean Park, WA 98640  
(360) 665-2804  
oysters@willapabay.org

Sheldon Marine Enterprises, Inc  
PO Box 1039  
Ocean Park, WA 98640



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20857+0001

